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November 15, 2019

Via Electronic Mail

Andre A. Rouviere, Esquire
Law Offices of Andre A. Rouviere
4070 Laguna Street
Coral Gables, Florida 33146

Re: *Rouviere v. DePuy Orthopaedics, Inc., et al.*

Dear Andre:

I am writing in response to your November 5, 2019 letter regarding alleged deficiencies in DePuy Orthopaedics, Inc., now known as Medical Device Business Services, Inc., ("DePuy") Answers and Objections to Plaintiffs' First Set of Interrogatories ("Answers and Objections"). DePuy disagrees with many of your characterizations of its Answers and Objections, but will provide further explanation of its objections, as warranted, in order to resolve these discovery disputes.

General issues concerning Plaintiffs' November 5, 2019 letter

First, although you have referenced DePuy's "*Boilerplate* objections," DePuy's objections were timely, properly pled, and addressed the legal issues of each specific interrogatory. DePuy's so-called "boilerplate objections" were repeated throughout DePuy's Answers and Objections simply because Plaintiffs' Interrogatories were almost universally overly broad and unduly burdensome, seeking information that is not within DePuy's possession or irrelevant to the Subject Component and Jodi Rouviere's claimed injuries in this case. Where able, DePuy will further elaborate on its so-called "boilerplate objections" below.

In response to your assertion that DePuy's production of documents contemporaneous to its Answers and Objections were improper as they were "not produced or maintained in the ordinary course of business," DePuy states that there is no requirement under the Federal Rules of Civil Procedure that require produced documents to *only* be "produced or maintained in the ordinary course of business." Having said that, DePuy produced documents like the Design History File for the Summit Stem as it is maintained in the ordinary course of business.

Although DePuy understands that you will produce a supplementary letter addressing your disputes relating to DePuy's Responses and Objections to Plaintiffs' First Requests for Production, DePuy notes here that Federal Rule of Civil Procedure 34(E)(ii) provides that "[i]f a request does not specify a form for producing electronically stored information, a party may produce it in a form or forms in which it is ordinarily maintained ***or in a reasonably usable form***." DePuy

submitted all of its responsive documents in clearly usable form, and Plaintiffs' objections are unwarranted.

You also object to DePuy's Supplemental Productions, alleging that DePuy invoked "gamesmanship" and that DePuy's supplements were "simply not produced despite [their] availability." This is not true. It takes time to both locate and gather documents relevant to Plaintiffs' voluminous requests. DePuy submitted supplemental productions as the records became available to DePuy and as expediently as possible.

DePuy also must point out that a number of your "clarified" Interrogatories do not simply "clarify" the original Interrogatory, but impermissibly alter the interrogatories to request new and additional information that is both beyond the scope of the original Interrogatory and also irrelevant to the claims brought by Plaintiffs in this lawsuit. Plaintiffs have already served the twenty-five interrogatories permitted by Federal Rule of Civil Procedure 25. To the extent that these "clarified" interrogatories seek new or additional information, Plaintiffs must move for leave to request this information and DePuy objects to any such attempts at this late state in fact discovery.

DePuy Biolox Head

This case – as far as DePuy is concerned – concerns only the DePuy Summit Femoral Stem ("Subject Component"). Although the Biolox Head is mentioned by name *one time* in the Amended Complaint, *see* Am. Compl.¶ 83, you do not allege injuries related to the Biolox Head. Rather, your Amended Complaint alleges injuries related specifically to the "Summit Tapered Hip System Stem." *See, e.g.*, Am. Compl. ¶¶ 162, 164, 167, 171, 173, 175. When Plaintiffs amended their Complaint, Plaintiffs specifically alleged additional injuries including titanium toxicity, metallosis, and heightened titanium, aluminum, and other metal levels, but still did not allege any injuries related to the Biolox Head. Am. Compl. ¶ 11, 90, 92, 104, 105. All of Plaintiffs' allegations against DePuy in this case concern only the Subject Component.

Additionally, in Plaintiffs' First Set of Interrogatories, Plaintiffs do not mention the Biolox Head at all. Instead, you defined the "Device" at issue as the "the DePuy Summit Tapered Hip System's Summit stem component." However, instead of utilizing your own defined term, throughout the Interrogatories you make reference to DePuy's "product," which is undefined. Accordingly, DePuy reasonably interpreted the requests for information regarding "product" as requests for information regarding DePuy's "Device." DePuy's "self-imposed limitations" in its responses to your Interrogatories were, in fact, not self-imposed, but based on your defined terms and the substance of your Interrogatories. Plaintiffs cannot now, in a meet and confer letter, attempt to revise these drafting choices made in your Amended Complaint and original Interrogatories to seek additional irrelevant documents and records from DePuy.

The Biolox Head component is irrelevant to Jodi Rouviere's alleged injuries, which include titanium toxicity, elevated metal levels, and alleged metallosis. It is *impossible* for the Biolox Head to cause these injuries in the first place, as it is a ceramic product that cannot scientifically cause injuries such as titanium toxicity, elevated metal levels, or metallosis. In fact, it appears that the Biolox Head *was not implanted in Jodi Rouviere during the August 17, 2012 surgery*. During

the August 17, 2012 implantation, Dr. Robert Buly considered implantation of the DePuy Biolox Head, but chose not to implant it, opting instead for the Stryker Restoration model: "It was decided to go with the larger head, Stryker MBM." *See* **Exhibit A**. In medical reports from the revision surgery on November 11, 2016, Dr. Carlos Alvarado confirmed that when he inspected Jodi Rouviere's hip to remove metal debris, he noted that Jodi Rouviere's original implant included an "MDM head." *See* **Exhibit B**. For all of these reasons, presumably, Plaintiffs make no allegations related to the Biolox Head in the Amended Complaint. Plaintiffs amended their complaint to add allegations – including allegations regarding titanium toxicity, metallosis, and heightened titanium, aluminum, and other metal levels – ***but did not allege any injuries related to the Biolox Head.*** Plaintiffs' Amended Complaint acknowledges that the Biolox Head is not relevant to this case.

In your "clarified" Interrogatories, you add numerous explicit references to the Biolox Head, which is a component that (1) is irrelevant to Jodi Rouviere's alleged injuries, including chromium toxicity, elevated cobalt levels, and metallosis, as it is a ceramic head and thus *could not cause said injuries*; and (2) is referenced only one time in the Amended Complaint and (3) is not once referenced in Plaintiffs' First Set of Interrogatories. Although you blame "DePuy's self-imposed limitations" for DePuy's failure to produce documents related to the Biolox Head or other unidentified DePuy devices, DePuy's document productions and responses to date have focused on the Subject Component or Summit Stem that Plaintiffs contend caused Jodi Rouviere's alleged injuries. DePuy will not produce documents related to the Biolox Head, nor will DePuy respond to your "clarified" Interrogatories as they are new and improper discovery relating to an irrelevant product.

DePuy provides the following responses to address your individual objections below:

Interrogatory No. 1: DePuy's objections to Plaintiffs' Interrogatory No. 1 are not boilerplate. Plaintiffs' Interrogatory sought, in an overly broad and unduly burdensome manner, information maintained by entities other than DePuy, which would be impossible for DePuy to obtain. Plaintiffs vaguely reference "said product" but, as mentioned above, did not define "product," leaving Plaintiffs' Interrogatory vague and overly broad, in that it appears to seek information related to "any" components, subparts, or systems, without limitation. DePuy reasonably interpreted "product" as equivalent to Plaintiffs' defined term "Device" and answered appropriately. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory.

Interrogatory No. 2: DePuy's objections to Plaintiffs' Interrogatory No. 2 are not boilerplate. Plaintiffs' Interrogatory sought a list of "all" personnel involved in any facet of the development of the "product." Such a list is unduly burdensome for DePuy, a large company that has had countless employees involved in the stages of the manufacture and distribution of the Subject Component that Plaintiffs' Interrogatory identifies. Plaintiffs' overly broad request even seeks names of personnel in "clerical or secretarial" roles who would not have substantive information to add to your claims related to the Subject Component. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the entire Design History File, the Design History Record, its product complaint file, and the complaint history file for the Subject Component.

Interrogatory No. 3: DePuy's objections to Plaintiffs' Interrogatory No. 3 are not boilerplate. Again, Plaintiffs' undefined use of the word "product" is both ambiguous and vague. Further, DePuy stated that the U.S. Food and Drug Administration regulations govern the design, manufacture, and distribution of the Subject Component. DePuy adds that the address for the U.S. FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory.

Interrogatory No. 4: DePuy's objections to Plaintiffs' Interrogatory No. 4 are not boilerplate. Like in Plaintiffs' Interrogatory No. 2, Plaintiffs seek here an overly broad and unduly burdensome list of all individuals who participated in the design of the Subject Component. DePuy cannot possibly identify every one of these individuals, in addition to their addresses and specific employment, as requested. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory.

Interrogatory No. 5: DePuy's objections to Plaintiffs' Interrogatory No. 5 are not boilerplate. Plaintiffs' Interrogatory, as written, is confusing and seeks multiple different facets of information. The clarification in Plaintiffs' November 5 letter further emphasizes the compound nature of this Interrogatory, in that you seek (1) information regarding steps of manufacture and assembly; (2) the use of various coatings on the Subject Component and sales records related to each; and (3) identification of all persons or entities who had knowledge of and/or tested the Subject Component. As noted above, the original Interrogatory does *not* seek information regarding the Biolox Head, and DePuy will not provide such information, as it is both irrelevant and unrequested as written in the original Interrogatory. Plaintiffs cannot attempt to seek additional information through Plaintiffs' meet and confer letter. DePuy reasonably interpreted "product" as equivalent to Plaintiffs' defined term "Device" and answered appropriately. This is especially true with respect to this Interrogatory, which begins "With regards to the Summit Tapered Stem … ." DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the complete sales history for the Subject Component and the Design History File and Design History Record for the Subject Component.

Interrogatory No. 6: DePuy's objections to Plaintiffs' Interrogatory No. 6 are not boilerplate. Plaintiffs seek overly broad and unduly burdensome information related to testing and retrieval of "any and all hip systems that include the Summit Tapered Stem," which is impossible for DePuy to obtain. Plaintiffs further seek the overly broad information of individual information for each person who tested "each and every unit," which is both irrelevant and impossible for DePuy to obtain. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the complete Design History File and Design History Record for the Subject Component.

Interrogatory No. 7: DePuy accepts Plaintiffs' withdrawal of Interrogatory No. 7.

Interrogatory No. 8: DePuy's objections to Plaintiffs' Interrogatory No. 8 are not boilerplate. Plaintiffs' Interrogatory seeks overly broad information related to number of "products" manufactured and sold by DePuy. As noted above, "products" is undefined. DePuy reasonably interpreted "product" as equivalent to Plaintiffs' defined term "Device" and answered

appropriately. Further, Plaintiffs' Interrogatory seeks information related to "each and every component part of the product's sub-assembly or assembly…that used the Summit Tapered Stem in their system." DePuy cannot possibly identify each and every component ever used in conjunction with the Subject Component, and accordingly, this request was both overly broad and unduly burdensome. Further, Plaintiffs impermissibly attempt to request information related to the Biolox Head in their "clarification." DePuy will not produce such information. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the complete sales history report for the Subject Component.

Interrogatory No. 9: DePuy's objections to Plaintiffs' Interrogatory No. 9 are not boilerplate. DePuy does not have access to information related to the use of the Subject Component "within any other hip system" by other manufacturers. DePuy does not know what Plaintiffs mean by "within any other system" and Plaintiffs' clarification in its meet in confer letter for Interrogatory No. 8 does not help define systems involving "other manufacturers," which Plaintiffs specifically request in Interrogatory No. 9. Additionally, DePuy has produced the 510K approval documents for the Subject Component. The 510k correspondence for each of the other individual components is irrelevant to the allegations in the Amended Complaint.

Interrogatory No. 10: DePuy does not know what Plaintiffs mean when they say DePuy's objections are "not well taken." DePuy need not withdraw its objections to overly broad and unduly burdensome requests merely because Plaintiffs do not like them. Plaintiffs impermissibly attempt to use vague, undefined terms to sweep in irrelevant information and imply that there are documented design problems related to the Subject Component. Plaintiffs did not define "concerns" related to safety or adverse events, and DePuy cannot reasonably tailor its production of documents to such a subjective standard. Nor can DePuy identify information or documents related to the vague and subjective "design issues or flaws or possible harm" when Plaintiffs do not define any of those terms. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including its entire complaint file, the complete Design History File, and the Design History Record for the Subject Component, which includes information regarding Quality Assurance Processes for the Subject Component.

Interrogatory No. 11: DePuy's objections to Plaintiffs' Interrogatory No. 11 are not boilerplate. Once again, Plaintiffs' Interrogatory seeks information related to individuals to have custody of "all records" related to the Subject Component, and includes a multifaceted list of possible records. DePuy does not maintain such an extensive grouping of records. Instead, DePuy has produced the information requested by Plaintiffs in their actual recorded form. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the Instructions for Use, which contains a majority of the requested information.

Interrogatory No. 12: DePuy's objections to Plaintiffs' Interrogatory No. 12 are not boilerplate. Plaintiffs' interrogatory seeks overly broad information impossible for DePuy to obtain, including but not limited to, for example warnings provided to "any possible user or any person or firm that the Defendant expected to come in contact with the product." DePuy cannot possibly be expected to predict every individual who may come in contact with the Subject Component, nor would DePuy have record of such individuals or the warnings that they were

provided. Again, DePuy responds that it produced information documents containing responsive information currently known to it, including but not limited to the Instructions for Use, which contained warnings and precautions, the Design History File and Design History Record, and the complaint file and complaint record for the Subject Component.

Interrogatory No. 13: DePuy's objections to Plaintiffs' Interrogatory No. 13 are not boilerplate. Plaintiffs' Interrogatory was overly broad, unduly burdensome, and vague in that it seeks information related to "operations," "programs," and "activities which involved the products." Plaintiffs have used such vague and undefined terms throughout their Interrogatories, yet somehow expect DePuy to accurately understand what Plaintiffs meant by generic terms such as "operations" or "programs" and "activities." DePuy reasonably interpreted "product" as equivalent to Plaintiffs' defined term "Device" and answered appropriately. Accordingly, DePuy responded to this Interrogatory with responsive information and documents currently known to it, including but not limited to the Subject Component's Instructions for Use, which contain warnings and labeling related to the Subject Component and is provided to implanting surgeons.

Interrogatory No. 14: DePuy's objections to Plaintiffs' Interrogatory No. 14 are not boilerplate. Plaintiffs' Interrogatory seeks an unduly burdensome list of "all claims or representations made" regarding the Subject Component from the Subject Components "inception" onward, which DePuy cannot possibly identify in full. Further, Plaintiffs' Interrogatory is overly broad in that it seeks this information not just as related to the Subject Component, but as to all "similar products including component parts and coatings." DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the Instructions for Use, the complete Design History File and Design History Record, and the complete complaint history record.

Interrogatory No. 15: DePuy's objections to Plaintiffs' Interrogatory No. 15 are not boilerplate. Plaintiffs' Interrogatory seeks an overly broad and unduly burdensome list of "all design modifications or alterations that have been considered" for the Subject Component and any component parts, which DePuy cannot possibly identify. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the complete Design History File and Design History Record for the Subject Component.

Interrogatory No. 16: DePuy's objections to Plaintiffs' Interrogatory No. 16 are not boilerplate. Although Plaintiffs claim in their meet and confer letter that this Interrogatory "clearly" requests the single subject of applicable standards, their clarification emphasizes that Plaintiffs seek multiple categories of information, including (1) regulations and standards applicable to safety of DePuy's products; and (2) information related to the testing of DePuy's products, including the identity of laboratories or consumer protection group which regularly tests DePuy products. Additionally, this Interrogatory as written was confusing, seeking a laundry list of information not clearly separable or identifiable. Further, Plaintiffs impermissibly attempt to request information related to the Biolox Head in their "clarification." DePuy will not produce such information. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including the complete Design History File and Design History Record for the Subject Component.

Interrogatory No. 17: DePuy's objections to Plaintiffs' Interrogatory No. 17 are not boilerplate. Plaintiffs' Interrogatory seeks, in an overly broad and unduly burdensome manner, the identity of any DePuy employee, agent, independent contractor, or "other representative" that is a member of any sort of committees or professional societies related to the Subject Component and other DePuy products *and* a complete list of any publications created by such individuals. DePuy cannot possibly gather such an extensive compilation of information related to *any* individual who worked for or represented DePuy in *any* capacity. Further, DePuy does not know what undefined terms such as "testing or standards committee" or "industrial professional society" mean in order to even attempt to identify such information for Plaintiffs. Somewhat ironically, it appears as though Plaintiffs' objections to DePuy's "boilerplate objections" are also boilerplate, as Plaintiffs cite that DePuy objected to this Interrogatory for being "compound," when DePuy did not make that objection here.

Interrogatory No. 18: DePuy's objections to Plaintiffs' Interrogatory No. 18 are not boilerplate. Plaintiffs' Interrogatory seeks overly broad information related to "any" written policies that apply to DePuy employees, hospital staff and doctors over whom DePuy has no control, DePuy's distributors, and independent distributors over whom DePuy would have no control. DePuy does not have access to all of this information, and was accordingly only able to respond with information within its knowledge. The remainder of this information is unduly burdensome, if not entirely impossible, for DePuy to obtain. Further, this Interrogatory seeks a second category of information related to communications between DePuy and other entities and individuals related broadly to "problems, hazards, failures, adverse event report or defects related to the device or any of its parts," and a third category of information related to statistical reports related to defects, rejections, or failures of the Subject Component. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including its complaint files and the Design History File and Design History Record for the Subject Component. Additionally, Plaintiffs requested information related to Adverse Event Reports, which are publicly available through the FDA website.

Interrogatory No. 19: DePuy's objections to Plaintiffs' Interrogatory No. 19 are not boilerplate. Plaintiffs' Interrogatory broadly seeks "any" reports, memoranda, or test data related to "any of the parts, components, sub-assemblies, or assemblies which would reflect the failure rate of the device." Plaintiffs did not define terms such as "defects, failure, or corrective action" and "failure rate," which are terms that may be applied differently and subjectively by different entities within the industry. DePuy cannot be expected to read Plaintiffs' minds as to what information they seek through these vague and undefined terms. Additionally, DePuy notes that, here, Plaintiffs used the defined term "device," and so DePuy produced information and documents related to the Subject Component only. DePuy reasonably interpreted "product" as equivalent to Plaintiffs' defined term "Device" and answered appropriately. Plaintiffs now impermissibly attempt to request information related to the Biolox Head in their "clarification." DePuy will not produce such information, as it was not requested in Plaintiffs' Interrogatory as written and is irrelevant. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including its complete Design History File and Design History Record, which contain information responsive to this Interrogatory.

Interrogatory No. 20: DePuy's objections to Plaintiffs' Interrogatory No. 20 are not boilerplate. DePuy cannot be expected to identify any time it has ever been "criticized" or "reprimanded" by any "body," nor could DePuy obtain such information. Plaintiffs' Interrogatory, as written, is overly broad and unduly burdensome in seeking such information. Further, Plaintiffs' clarification adds the additional request that DePuy provide information related to "DePuy's investigation" of any criticisms, which is not requested in the original Interrogatory, as written. DePuy reiterates that it has not been "cited, criticized, reprimanded…or had any legal action taken against it by any public official" or "governmental agency," because of violations of federal, state, or local regulations related to the Subject Component.

Interrogatory No. 21: DePuy's objections to Plaintiffs' Interrogatory No. 21 are not boilerplate. Plaintiffs' Interrogatory seeks impossible to obtain "verbal" complaints related to the Subject Component or any hip systems containing the Subject Component. Additionally, Plaintiffs' overly broad request seeks a list of any individual who has ever complained of a defect in *any* hip system that includes the Subject Component, whether or not the Subject Component was the cause of the defect. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including its complete complaint files.

Interrogatory No. 22: DePuy's objections to Plaintiffs' Interrogatory No. 22 are not boilerplate. Plaintiffs' Interrogatory, which takes up half a page, single-spaced, includes an overly broad laundry list of various safety tests regardless of whether they are tests actively performed on the Subject Component and additionally seeks information related to the name and contact information of any individual involved in any testing performed. DePuy additionally does not have access to any testing performed by third party or independent entities, and it would be unduly burdensome for DePuy to obtain any testing results completed by "outside facilities" and "regulatory agencies," which are undefined and vague. Plaintiffs seek a second category of information related to "revision documents to original applications or reports," thereby making Plaintiffs' Interrogatory compound. Further, Plaintiffs impermissibly attempt to request information related to the Biolox Head in their "clarification." DePuy will not produce such information, as it was not requested in Plaintiffs' Interrogatory as written and is irrelevant. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including its complete complaint files, as well as the Design History File and Design History Record, which include information responsive to Plaintiffs' request.

Interrogatory No. 23: DePuy accepts Plaintiffs' withdrawal of Interrogatory No. 23.

Interrogatory No. 24: DePuy's objections to Plaintiffs' Interrogatory No. 24 are not boilerplate. Plaintiffs' Interrogatory seeks information related to disparate categories of information, as emphasized by Plaintiffs' clarification: (1) trade affiliations related to the development of product information and warnings, and (2) any online marketing information performed through social media. Additionally, Plaintiffs' request seeks information related to any individual who has ever "logged into" a social media platform from 2007 onward on behalf of DePuy, which is both unduly burdensome and overly broad. DePuy cannot possibly expected to locate such information over a twelve-year period, nor know the details of every individual log-in. Further, Plaintiffs impermissibly attempt to request information related to the Biolox Head in their "clarification." DePuy reasonably interpreted "product" as equivalent to Plaintiffs' defined term

"Device" and answered appropriately. DePuy will not produce such information, as it was not requested in Plaintiffs' Interrogatory as written and is irrelevant.

Interrogatory No. 25: DePuy's objections to Plaintiffs' Interrogatory No. 25 are not boilerplate. Plaintiffs' Interrogatory as written requests three categories of disparate information: (1) materials provided to patients receiving the Subject Component in 2012; (2) the source of any warnings related to labeling and packaging; and (3) DePuy's distribution of any materials containing warnings to any entity and how. Plaintiffs' Interrogatory, as written, seeks unduly burdensome and overly broad information related to "verbal" warnings provided by any DePuy employee in manufacturing, distribution, or sales, which DePuy could not possibly identify or obtain. Further, Plaintiffs impermissibly attempt to request information related to the Biolox Head in their "clarification." DePuy notes that, here, Plaintiffs used the defined term "device." Accordingly, DePuy will not produce such information, as it was not requested in Plaintiffs' Interrogatory as written and is irrelevant. DePuy has produced responsive information and documents currently known to it in regard to this Interrogatory, including its Instructions for Use, which including warnings and precautions, and were effective as of August 2012.

As explained in detail above, DePuy's objections were made in good faith. DePuy reiterates that Plaintiffs may not use a meet and confer letter as an attempt to seek additional information from DePuy that was not originally requested, especially related to a component not originally referenced in Plaintiffs' First Set of Interrogatories and from which none of Jodi Rouviere's injuries originate.

Very truly yours,

Joseph G. Eaton

cc: Jodi Rouviere (*via e-mail*)
Paul Asfendis, Esq.
J.T. Larson, Esq.